

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Joseph P. Orban III	Examiner:	Fangemonique A. Smith
Serial No.:	10/508,445	Group:	Art Unit 3736
Filed:	September 16, 2004	Dated:	January 5, 2010
For:	Minimally Invasive Removal Device with Breakaway Sheath	<i>Filed Via EFS-Web</i> <u>Confirmation No.: 6710</u>	

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

Dear Sir/Madam:

This Appeal Brief concerns an appeal from a Final Office Action that was mailed on July 24, 2009 (hereinafter “the Final Office Action”), and an Advisory Action that was mailed on October 30, 2009 (hereinafter “the Advisory Action”) in connection with the above-identified application.

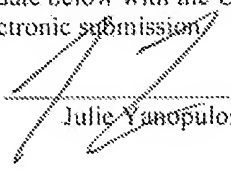
I. REAL PARTY IN INTEREST

The real party in interest for this application is Tyco Healthcare Group LP (d/b/a Covidien), having a principal office at 60 Middletown Avenue, North Haven, CT 06473.

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being transmitted on the date below with the United States Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450, via electronic submission.

Dated: January 5, 2010


Julie Yanopoulos

II. RELATED APPEALS AND INTERFERENCES

There are no other prior or pending appeals or interferences related to the above-identified application.

III. STATUS OF CLAIMS

The status of the claims in the above-identified application is as follows:

- A) Claims 1-35 are pending; and
- B) Claims 1-35 stand rejected and are being appealed.

An accurate copy of claims 1-35 is provided in the Claims Appendix.

IV. STATUS OF AMENDMENTS

A Response Under 37 CFR §1.116 was filed on October 15, 2009 (hereinafter “the Response”) in reply to the Final Office Action. In the Response, Appellants presented arguments highlighting the patentable elements distinguishing the claimed subject matter from that which is disclosed in the references of record, and in view of those arguments, Appellants requested reconsideration of the recited subject matter. In the Advisory Action, the Examiner indicated that the arguments presented by Appellants in the Response had been considered, but nevertheless maintained that the application was not in condition for allowance.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent Claim 1 is directed to a tissue removal device. (see Page 7, lines 1-2, and FIGS. 1-4). The tissue removal device includes an elongate shaft having a distal end and a

proximal end, wherein the elongate shaft defines a longitudinal axis. (see Page 7, lines 2-4, and FIGS. 1-4). The tissue removal device includes a bag support defining an opening. (see Page 7, lines 2-4, and FIGS. 7-8). The bag support is collapsible and expandable to open and close the opening. (see Page 7, lines 11-14, and FIGS. 1-4). The tissue removal device includes a bag operatively attached to the bag support. (see Page 7, lines 4-5 and lines 19-20, and FIGS. 1-4). The bag is repositionable between an unfolded position, in which the bag extends away from the bag support, and a folded position, in which the bag is folded onto itself. (see Page 8, lines 6-9, and FIGS. 1-4). The bag has a first edge and a second edge (see Page 13, lines 2-4), an open first end operatively secured to the bag support (see Page 7, line 24 to Page 8, line 1) and a closed end (see Page 8, line 1), the first end being connected to the support so that when the bag support is in a collapsed position the bag opening is substantially closed (see Page 8, lines 8-9). The bag has folds including at least one transverse fold extending at least partially from the first edge toward the second edge such that an angle less than 90° is defined relative to the longitudinal axis. (see Page 13, lines 7-14, and FIG. 4). A distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold. (see Page 13, lines 18-20).

Independent claim 19 is directed to a method of collapsing a bag of a tissue removal device. The method comprises the steps of providing a minimally invasive tissue removal device. (see Page 7, lines 1-2, and FIGS. 1-4). The tissue removal device includes a shaft having a distal end and a proximal end and defining a longitudinal axis (see Page 7, lines 2-4, and FIGS. 1-4); a bag support (see Page 7, lines 2-4, and FIGS. 7-8); and a bag attached to the

bag support and being repositionable between an unfolded position, in which the bag extends away from the bag support, and a folded position, in which the bag is folded onto itself, the bag having a first edge and a second edge, an upper end operatively coupled to the bag support and a lower end (see Page 7, lines 4-5 and lines 19-20, Page 8, lines 6-9, and FIGS. 1-4). The method further includes the step of folding the bag transversely with respect to the longitudinal axis such that a first transverse fold is formed that extends at least partially from the first edge toward the second edge such that an angle less than 90° is defined relative to the longitudinal axis longitudinal axis. (see Page 13, lines 7-14, and FIG. 4). A distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold. (see Page 13, lines 18-20).

Independent claim 28 is directed to a minimally invasive tissue removal device (see Page 7, lines 1-2, and FIGS. 1-4) for passage through a cannula (see Page 9, lines 3-5). The device includes an elongate shaft having a distal end portion and a proximal end portion, the elongate shaft defining a longitudinal axis. (see Page 7, lines 2-4, and FIGS. 1-4). The device further includes a bag assembly operatively coupled to the distal end portion of the shaft. (see Page 7, lines 2-3, and FIGS. 1-4). The bag assembly includes a bag support structure having a first position and a second position. (see Page 7, lines 2-4, and FIGS. 7-8). The bag assembly includes a bag configured for repositioning between an unfolded position, in which the bag extends away from the bag support, and a folded position, in which the bag is folded onto itself. (see Page 7, lines 4-5 and lines 19-20, and FIGS. 1-4), (see Page 8, lines 6-9, and FIGS. 1-4). The bag has an upper end and a lower end, the upper end having an open position and a closed

position and being operatively secured to the bag support such that when the bag support is in the open position, the upper end of the bag is substantially open and when the bag support is in the closed position, the upper end of the bag is substantially closed. (see Page 7, lines 4-5 and lines 19-20, Page 8, lines 6-9, and FIGS. 1-4). The bag is folded over onto itself so as to form at least one transverse fold defining a fold axis, wherein the fold axis defines an angle between 0° and 90° relative to the longitudinal axis (see Page 13, lines 7-14, and FIG. 4) such that an axial length of the bag assembly is increased and a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, that is relatively smaller as compared to a distal portion of the tissue removal device including a like bag, in a folded position, that is devoid of said at least one transverse fold. (see Page 13, lines 18-20).

Independent claim 31 is directed to a minimally invasive tissue removal device (see Page 7, lines 1-2, and FIGS. 1-4) for passage through a trocar (see Page 9, lines 3-5). The device includes an elongate shaft having a distal end portion and a proximal end portion, the elongate shaft defining a longitudinal axis. (see Page 7, lines 2-4, and FIGS. 1-4). The device includes a bag support at the distal end of the shaft having a first position and a second position, the bag defining a plane in the first position. (see Page 7, lines 2-3, and FIGS. 1-4). The device includes a bag having an open end and a closed end opposite the open end, the bag extending along a bag axis which is perpendicular to the longitudinal axis, the bag having an open position and a closed position and being configured for repositioning between an unfolded position, in which the bag extends away from the bag support, and a folded position, in which the bag is folded onto itself. (see Page 7, lines 4-5 and lines 19-20, and FIGS. 1-4), (see Page 8, lines 6-9, and FIGS. 1-4). The bag is folded over onto itself so as to form at least one fold extending along an axis that is

substantially non-parallel and non-orthogonal to the longitudinal axis of the shaft. (see Page 13, lines 7-14, and FIG. 4). A distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold. (see Page 13, lines 18-20).

Independent claim 33 is directed to a method of collapsing a bag of a tissue removal device. The method includes the steps of providing a minimally invasive tissue removal device. (see Page 7, lines 1-2, and FIGS. 1-4). The device has a bag assembly. (see Page 7, lines 2-3, and FIGS. 1-4). The bag assembly includes a shaft defining a longitudinal axis (see Page 7, lines 2-4, and FIGS. 1-4); a bag support disposed at a distal end of the shaft (see Page 7, lines 2-3, and FIGS. 1-4); and a bag attached to the bag support (see Page 7, lines 4-5 and lines 19-20), the bag being repositionable between an unfolded position, in which the bag assembly defines an initial longitudinal dimension, and a folded position, in which the bag assembly defines a subsequent longitudinal dimension, the subsequent longitudinal dimension being greater than the initial longitudinal dimension (Page 8, lines 6-9, and FIGS. 1-4). The method further includes the step of folding the bag such that at least one transverse fold is formed, the at least one transverse fold extending transversely with respect to the longitudinal axis. (see Page 13, lines 7-14, and FIG. 4). A distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold. (see Page 13, lines 18-20).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellant requests review of the following outstanding grounds of rejection:

A) The rejection of claims 1-5, 7-9, 12-16 and 18-35 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,215,521 to Cochran, *et al.* (hereinafter “Cochran”) in view of U.S. Patent No. 5,149,159 to Bardes, *et al.* (hereinafter “Bardes”);

B) The rejection of claims 1, 4, and 6 under 35 U.S.C. §103(a) as being unpatentable over Cochran in view of Bardes and further in view of U.S. Patent No. 5,899,694 to Summer (hereinafter “Summer”);

C) The rejection of claims 10 and 11 under 35 U.S.C. §103(a) as being unpatentable over Cochran in view of Bardes and further in view of U.S. Patent No. 6,402,722 to Snow *et al.* (hereinafter “Snow”); and

D) The rejection of claim 17 under 35 U.S.C. §103(a) as being unpatentable over Cochran in view of Bardes and further in view of U.S. Patent No. 5,480,404 to Kammerer, *et al.* (hereinafter “Kammerer”).

VII. ARGUMENT

A. Claims 1-5, 7-9, 12-16 and 18-35 are patentable under 35 U.S.C. §103(a) over U.S. Patent No. 5,215,521 to Cochran, *et al.* in view of U.S. Patent No. 5,149,159 to Bardes, *et al.*

Claims 1-5, 7-9, 12-16 and 18-35 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,215,521 to Cochran, *et al.* (hereinafter “Cochran”) in view of U.S. Patent No. 5,149,159 to Bardes, *et al.* (hereinafter “Bardes”). Appellant respectfully

submits, however, that the combination of Cochran and Bardes fails to render the subject matter of claims 1-5, 7-9, 12-16, and 18-35 obvious.

Pursuant to 35 U.S.C. §103(a), “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art,” then the subject matter is not patentable. (Emphasis added).

Independent claim 1 recites “[a] tissue removal device” that includes, *inter alia*, a bag “having folds including at least one transverse fold” that is repositionable between an unfolded position and a folded position, “whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold.”

Independent claim 19 recites “[a] method of collapsing a bag of a tissue removal device” that includes the steps of, *inter alia*, providing a tissue removal device with a bag that is repositionable between unfolded and folded positions, and:

folding the bag transversely with respect to the longitudinal axis such that a first transverse fold is formed . . . whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold.

Independent claim 28 recites “[a] minimally invasive tissue removal device” that includes, *inter alia*, a bag that is repositionable between unfolded and folded positions, wherein the bag is:

folded over onto itself so as to form at least one transverse fold . . . such that an axial length of the bag assembly is increased and a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, that is relatively smaller as compared to a distal portion of the tissue removal device including a like bag, in a folded position, that is devoid of said at least one transverse fold.

Independent claim 31 recites “[a] minimally invasive tissue removal device” that includes, *inter alia*, a bag that is repositionable between unfolded and folded positions, wherein:

the bag is folded over onto itself so as to form at least one fold extending along an axis that is substantially non-parallel and non-orthogonal to the longitudinal axis of the shaft, whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold.

Independent claim 33 recites “[a] method of collapsing a bag of a tissue removal device” that includes the steps of, *inter alia*, “providing a minimally invasive tissue removal device” including a bag that is repositionable between unfolded and folded positions, and:

folding the bag such that at least one transverse fold is formed, the at least one transverse fold extending transversely with respect to the longitudinal axis, whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold.

Cochran relates to an organ retrieval apparatus including an entrapment envelope 22 that is inserted into an inflated body cavity through an elongate sheath 20. (See col. 8, lines 12-18; FIG. 4 reproduced below).

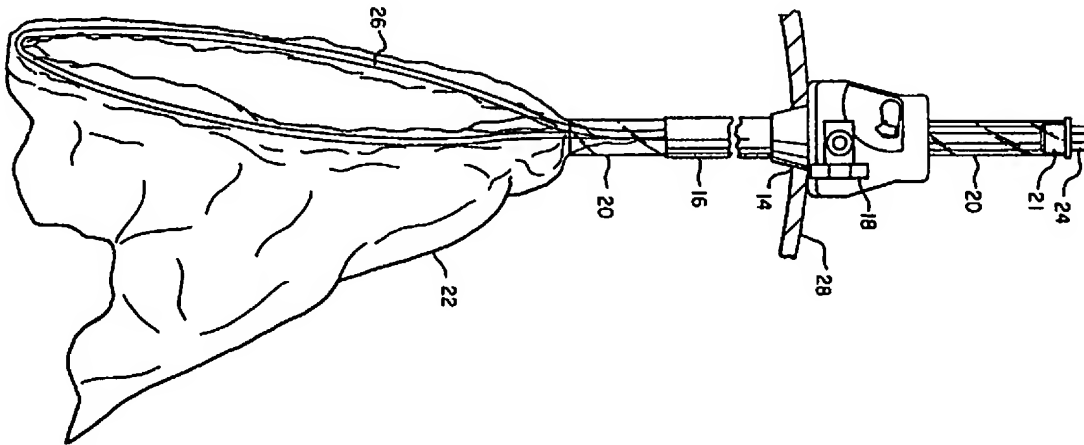
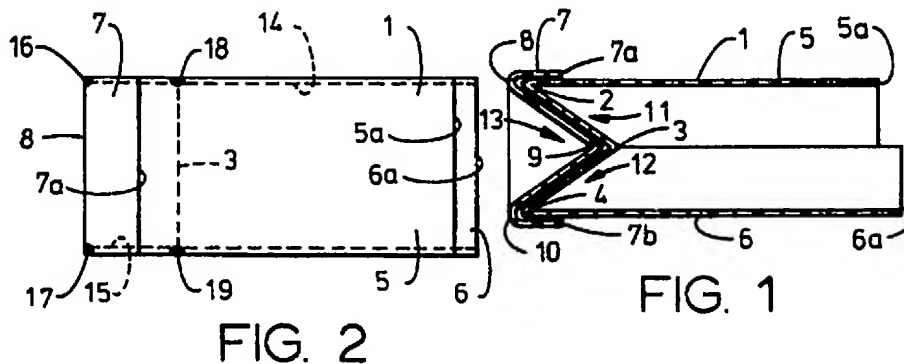
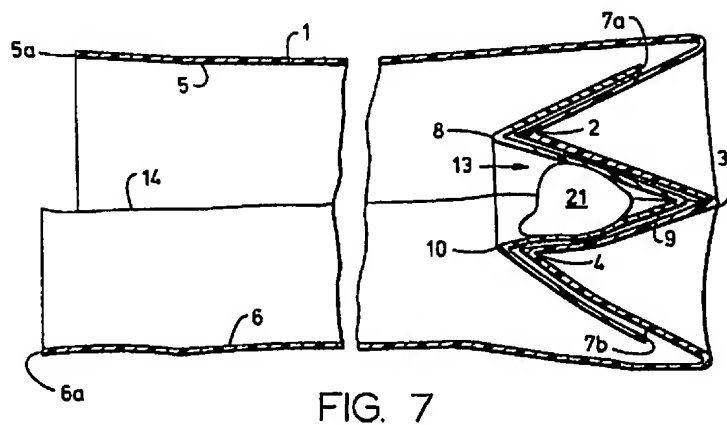
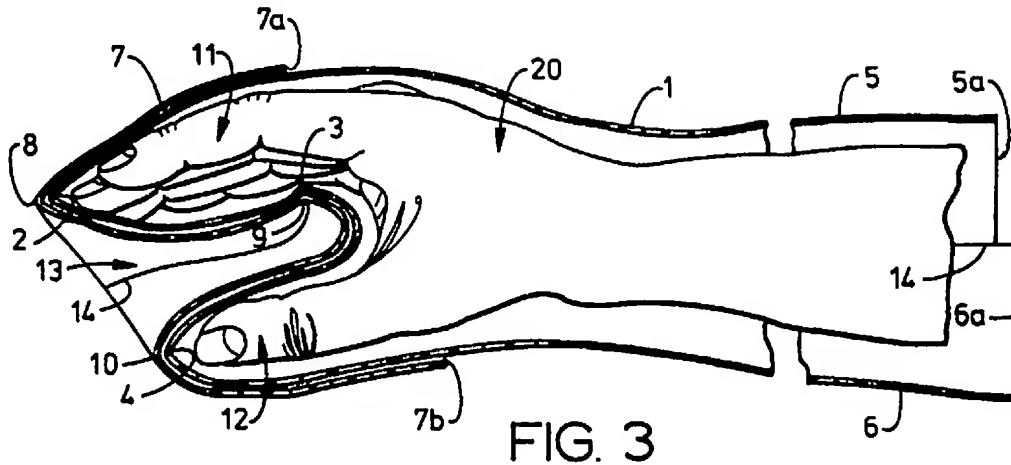


FIG. 4

Bardes relates to “a disposable collector and container in the form of a glove-like bag.” (Col. 1, lines 8-9). Specifically, Bardes discloses a collector including a strip 1 that is connected to a second ply 7. (See col. 3, lines 49-64; FIGS. 1, 2 below). The strip 1 is folded along transverse fold lines 2, 3, 4 to form a closed end with a gusset having a “W” shape. (See col. 3, lines 54-56; FIGS. 1, 7 below). The closed, gusseted end of the collector forms three pockets, i.e., two interior pockets 11, 12 and one exterior pocket 13. (See col. 4, lines 4-7; FIGS. 1, 3, 7 below).





In the Final Office Action, the entrapment envelope 22 described in Cochran was characterized as the “bag” recited in claims 1-5, 7-9, 12-16, and 18-35. While the Examiner argued that the Cochran envelope 22 is capable of folding transversely, the Examiner acknowledged that the envelope 22 fails to include the at least one transverse fold also included as part of the claimed subject matter, but relied upon Bardes for disclosure of this concept. (See Final Office Action, page 3).

Regarding Bardes, with reference to FIG. 7 (reproduced above), the Examiner stated that:

Bardes et al. disclose [*sic*] a sample retrieval instrument having a bag with at least one transverse fold at its distal end. The transverse fold is located such that the cross sectional area of the

distal end of the apparatus is reduced when the fold is present forming a pouch area which allows a specimen to be collected. The pouch includes a first and second edge with bag folds including at least one transverse fold extending from the first edge toward the second edge such that an angle less than 90 degrees is defined relative to the longitudinal axis (Figure 7). Devoid the fold, the area would have a larger cross section. (Final Office Action, pages 3-4).

Appellant respectfully disagrees with the Examiner's characterization of Bardes.

As discussed in the Amendment that was filed on April 1, 2009, according to the present disclosure, the bag 40 recited in the pending claims is repositionable between unfolded and folded positions, e.g., in preparation for packaging, as seen below in the transition between FIGS. 3 and 4. (See page 13, lines 15-18). Specifically, the present disclosure states that repositioning the bag 40 along a transverse fold 47 "has been found to produce a low profile folded bag, such that smaller diameter tubes can be used." (Page 13, lines 18-20). In other words, including the transverse fold 47 in the bag 40 allows for a reduction in the transverse profile and dimensions of the bag 40 when the bag 40 is in a folded condition on or around bag support 20.

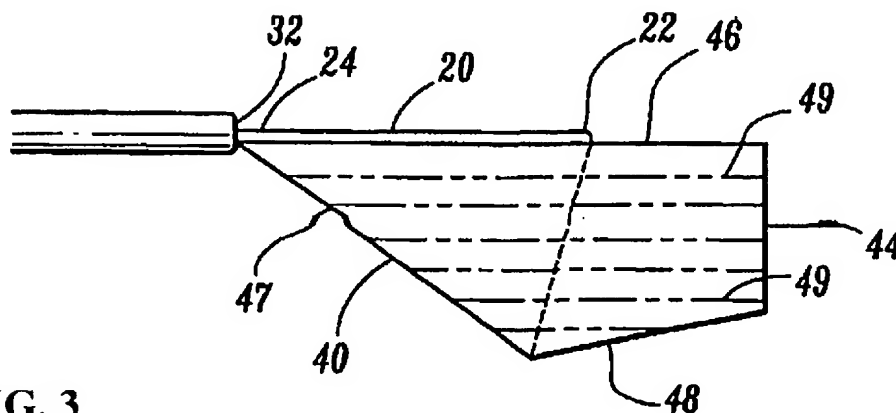
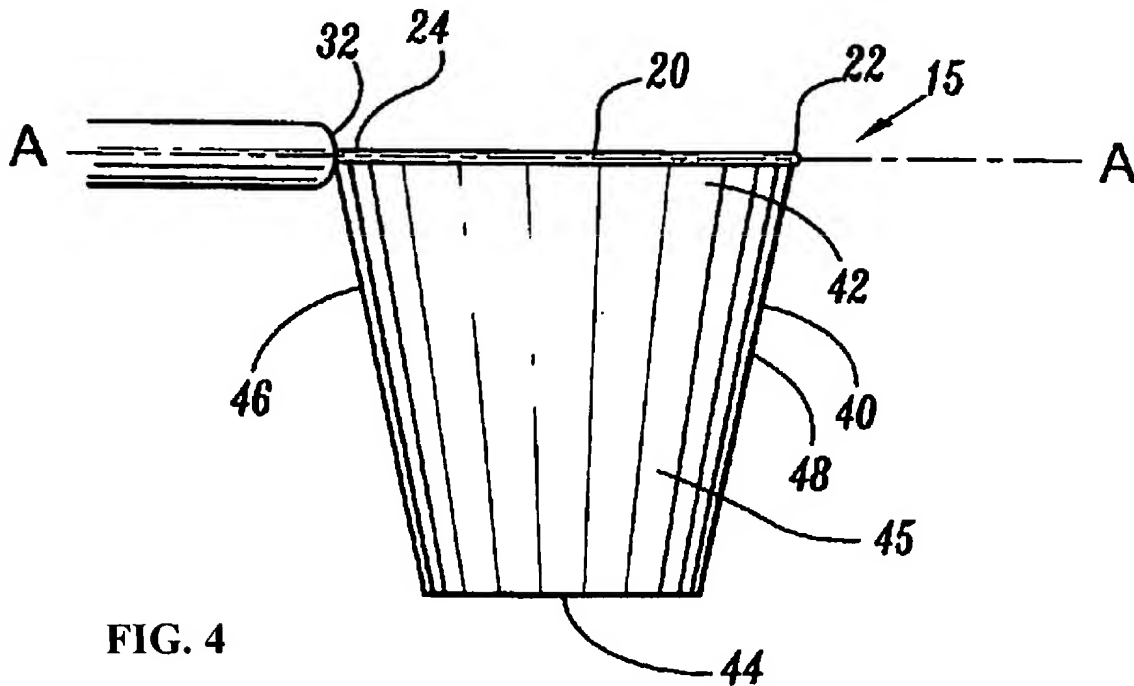


FIG. 3



In contrast, Bardes indicates that the folds 2, 3, 4 form the aforementioned gusset and the pockets 11, 12, 13 in the collector.

With reference to the annotated version of FIG. 4 reproduced below, Appellant respectfully submits that while the folds 2, 3, 4 allow the overall length “L” of the collector to be reduced by folding the strip 1 inwardly and proximally, the folds 2, 3, 4 do nothing to reduce either the width “W” or height “H” of the collector. Thus, Appellant respectfully submits that the folds 2, 3, 4 fail to reduce any dimension of the Bardes collector that may be properly characterized as “transverse.”



To the contrary, Appellant respectfully submits that by folding the strip 1 along the fold lines 2, 3, 4, material is drawn inwardly and proximally into the interior portion of the strip 1 to thereby define the gusseted “W” shape seen in FIG. 4 above. This additional material actually increases the width “W” of the collector, and not only creates the exterior 13, which houses the specimen to be collected, but allows for manipulation of the clinician’s fingers to facilitate grasping of the specimen. Were the folds 2, 3, 4 to reduce one or more transverse dimensions of the collector, as alleged in the Final Office Action, the clinician’s ability to open and close her hand would be substantially limited, if not entirely eliminated, thus frustrating the very purpose of the disclosed collector.

Appellant notes the disclosure in Bardes indicating that after a specimen has been collected, the open proximal end of the collector is pulled distally, i.e., towards the clinician's fingers, to turn the collector inside out. (*See* col. 5, lines 59-68). However, in this position, as above in FIG. 7, the end of the collector including the gusseted "W" shaped portion tapers outwardly relative to the longitudinal axis, thereby increasing the transverse dimension of the collector.

Accordingly, Appellant respectfully submits that Bardes fails to disclose, or even suggest, a bag "having folds including at least one transverse fold" that is repositionable between an unfolded position and a folded position, "whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position," as recited in independent claim 1, (emphasis added), or "[a] method of collapsing a bag of a tissue removal device" that includes the steps of, *inter alia*, providing a tissue removal device with a bag that is repositionable between unfolded and folded positions, and folding the bag such that at least one transverse fold is formed, "whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position," as recited in independent claim 19. (Emphasis added).

Additionally, Appellant respectfully submits that Bardes fails to disclose, or even suggest, a bag that is repositionable between unfolded and folded positions, wherein the bag is "folded over onto itself so as to form at least one transverse fold . . . such that an axial length of the bag assembly is increased and a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension," as recited in independent claim 28, (emphasis added), or "a bag that is repositionable between unfolded and folded positions, wherein the bag is folded

over onto itself so as to form at least one fold extending along an axis that is substantially non-parallel and non-orthogonal to the longitudinal axis of the shaft, whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position,” as recited in independent claim 31. (Emphasis added).

Likewise, Appellant respectfully submits that Bardes also fails to disclose, or even suggest, “a method of collapsing a bag of a tissue removal device” that includes the steps of, *inter alia*, “providing a minimally invasive tissue removal device” including a bag that is repositionable between unfolded and folded positions” and “folding the bag such that at least one transverse fold is formed, the at least one transverse fold extending transversely with respect to the longitudinal axis, whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position,” as recited in independent claim 33. (Emphasis added).

In view of the foregoing discussion concerning the Bardes collector, Appellant respectfully submits that Bardes fails to remedy the deficiencies in Cochran acknowledged in the Final Office Action. Accordingly, and for at least this reason, *inter alia*, Appellant respectfully submits that neither Cochran, nor Bardes, nor any proper combination thereof, discloses or suggests the subject matter of independent claims 1, 19, 28, 31, and 33 as a whole, and therefore, that the combination of Cochran and Bardes fails to render the subject matter of independent claims 1, 19, 28, 31, and 33 obvious. As such, Appellant respectfully submits that independent claims 1, 19, 28, 31, and 33 are allowable over Cochran in view of Bardes under 35 U.S.C. §103(a).

Since claims 2-5, 7-9, 12-16, 18, 20-27, 29, 30, 32, 34, and 35 depend either directly or indirectly from independent claims 1, 19, 28, 31, and 33, and include each element recited therein, for at least the reasons that independent claims 1, 19, 28, 31, and 33 are allowable over Cochran in view of Bardes under 35 U.S.C. §103(a), *inter alia*, Appellant respectfully submits that the subject matter of claims 2-5, 7-9, 12-16, 18, 20-27, 29, 30, 32, 34, and 35 as a whole is also allowable over Cochran in view of Bardes under 35 U.S.C. §103(a).

B. Claims 1, 4, and 6 are patentable under 35 U.S.C. §103(a) over Cochran in view of Bardes and further in view of U.S. Patent No. 5,899,694 to Summer

Claims 1, 4, and 6 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Cochran in view of Bardes and further in view of U.S. Patent No. 5,899,694 to Summer (hereinafter “Summer”). Appellant respectfully submits, however, that the combination of Cochran, Bardes, and Summer fails to render the subject matter of claims 1, 4, and 6 obvious.

In the Final Office Action, the Examiner acknowledged that the combination of Cochran and Bardes fails to disclose a sheath that is fabricated from a flexible heat-shrinking polymer, as recited in claims 4 and 6, but relied on Summer for disclosure of this concept.¹

As discussed above, the combination of Cochran and Bardes fails to suggest the subject matter of independent claim 1 as a whole. Assuming, *arguendo*, that the Examiner’s purported characterization of Summer is accurate, including the sheath purportedly disclosed therein would fail to cure the aforescribed deficiencies in the combination of Cochran and Bardes.

¹ Appellant believes that the Examiner inadvertently, but mistakenly, included claim 1 in the rejection under 35 U.S.C. §103(a) over Cochran in view of Bardes and Summer, in that independent claim 1 does not recite the sheath purportedly disclosed in Summer. However, in the interests of responding fully to the rejection, Appellant will overlook the inclusion of claim 1, and the rejection will be addressed with respect to claims 1, 4, and 6.

Accordingly, and for at least this reason, *inter alia*, Appellant respectfully submits that the combination of Cochran, Bardes, and Summer fails to suggest the subject matter of independent claim 1 as a whole, and therefore, that the combination of Cochran, Bardes, and Summer fails to render the subject matter of independent claim 1 obvious. Accordingly, Appellant respectfully submits that independent claim 1 is allowable over Cochran in view of Bardes and Summer under 35 U.S.C. §103(a).

Since claims 4 and 6 depend directly and indirectly from independent claim 1, respectively, and include each element recited therein, for at least the reasons that independent claim 1 is allowable over Cochran in view of Bardes and Summer under 35 U.S.C. §103(a), *inter alia*, Appellant respectfully submits that the subject matter of claims 4 and 6 as a whole is also allowable over Cochran in view of Bardes and Summer under 35 U.S.C. §103(a).

C. Claims 10 and 11 are patentable under 35 U.S.C. §103(a) over Cochran in view of Bardes and further in view of U.S. Patent No. 6,402,722 to Snow et al.

Claims 10 and 11 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Cochran in view of Bardes and further in view of U.S. Patent No. 6,402,722 to Snow *et al.* (hereinafter “Snow”). Appellant respectfully submits, however, that the combination of Cochran, Bardes, and Snow fails to render the subject matter of claims 10 and 11 obvious.

In the Final Office Action, the Examiner acknowledged that the combination of Cochran and Bardes fails to disclose “a cord operatively connected to the tear line for facilitating the tearing of the sheath along the tear line,” as recited in claim 10, but relied on Snow for disclosure of this concept.

As previously discussed, the combination of Cochran and Bardes fails to suggest the subject matter of independent claim 1 as a whole. Assuming, *arguendo*, that the Examiner's purported characterization of Snow is accurate, including the cord purportedly disclosed therein would fail to cure the aforescribed deficiencies in the combination of Cochran and Bardes.

Accordingly, and for at least this reason, *inter alia*, Appellant respectfully submits the combination of Cochran, Bardes, and Snow fails to suggest the subject matter of independent claim 1 as a whole, and therefore, that the combination of Cochran, Bardes, and Snow fails to render the subject matter of independent claim 1 obvious. As such, Appellant respectfully submits that independent claim 1 is allowable over Cochran in view of Bardes and Snow under 35 U.S.C. §103(a). Since claims 10 and 11 depend either directly or indirectly from independent claim 1, and include each element recited therein, for at least the reasons that independent claim 1 is allowable over Cochran in view of Bardes and Snow under 35 U.S.C. §103(a), *inter alia*, Appellant respectfully submits that claims 10 and 11 are also allowable over Cochran in view of Bardes and Snow under 35 U.S.C. §103(a).

D. Claim 17 are patentable under 35 U.S.C. §103(a) over Cochran in view of Bardes and further in view of U.S. Patent No. 5,480,404 to Kammerer, *et al.*

Claim 17 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Cochran in view of Bardes and further in view of U.S. Patent No. 5,480,404 to Kammerer, *et al.* (hereinafter "Kammerer"). Appellant respectfully submits, however, that the combination of Cochran, Bardes, and Kammerer fails to render the subject matter of claim 17 obvious.

In the Final Office Action, the Examiner acknowledged that the combination of Cochran and Bardes fails to disclose a bag having a trapezoidal shape, as substantially recited in claim 17,

but relied on Kammerer for disclosure of this concept.

As previously discussed, the combination of Cochran and Bardes fails to suggest the subject matter of independent claim 1 as a whole. Assuming, *arguendo*, that the Examiner's purported characterization of Kammerer is accurate, including the trapezoidal bag purportedly disclosed therein would fail to cure the aforescribed deficiencies in the combination of Cochran and Bardes.

Accordingly, and for at least this reason, *inter alia*, Appellant respectfully submits that the combination of Cochran, Bardes, and Kammerer fails to suggest the subject matter of independent claim 1 as a whole, and therefore, that the combination of Cochran, Bardes, and Kammerer fails to render the subject matter of independent claim 1 obvious. As such, Appellant respectfully submits that independent claim 1 is allowable over Cochran in view of Bardes and Kammerer under 35 U.S.C. §103(a). Since claim 17 depends directly from independent claim 1, and includes each element recited therein, for at least the reasons that independent claim 1 is allowable over Cochran in view of Bardes and Kammerer under 35 U.S.C. §103(a), *inter alia*, Appellant respectfully submits that the subject matter of claim 17 as a whole is also allowable over Cochran in view of Bardes and Kammerer under 35 U.S.C. §103(a).

In view of the foregoing remarks and arguments, Appellant respectfully submits that claims 1-35 are allowable over the references of record, and accordingly, respectfully requests reconsideration and allowance of these claims.

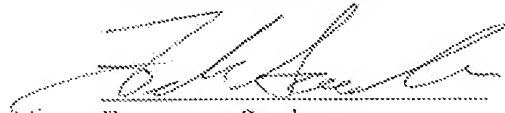
VIII. CONCLUSION

In view of the foregoing remarks, Appellant respectfully submits that all of the claims now pending in this application, namely, claims 1-35, are in condition for allowance. Early and favorable reconsideration of this application is respectfully requested.

Please charge any deficiency as well as any other fee(s) which may become due under 37 C.F.R. §1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s) to Deposit Account No. 21-0550. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge Deposit Account No. 21-0550 therefore.

An early and favorable response on the merits is earnestly requested.

Respectfully submitted,



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VIII. APPENDIX OF CLAIMS

Claim 1 (rejected): A tissue removal device, comprising:

an elongate shaft having a distal end and a proximal end, wherein the elongate shaft defines a longitudinal axis;

a bag support defining an opening, the bag support being collapsible and expandable to open and close the opening;

a bag operatively attached to the bag support and being repositionable between an unfolded position, in which the bag extends away from the bag support, and a folded position, in which the bag is folded onto itself, the bag having a first edge and a second edge, an open first end operatively secured to the bag support and a closed end, the first end being connected to the support so that when the bag support is in a collapsed position the bag opening is substantially closed; and

the bag having folds including at least one transverse fold extending at least partially from the first edge toward the second edge such that an angle less than 90° is defined relative to the longitudinal axis, whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold.

Claim 2 (rejected): The tissue removal device of claim 1, further comprising a tube for receiving the shaft, bag support and bag.

Claim 3 (rejected): The tissue removal device of claim 1, wherein the folds include folds approximately parallel with the longitudinal axis.

Claim 4 (rejected): The tissue removal device of claim 1, further including a sheath disposed about the bag assembly.

Claim 5 (rejected): The tissue removal device of claim 4, wherein the sheath includes a weakness for breaking away from the bag.

Claim 6 (rejected): The tissue removal device of claim 4, wherein the sheath is fabricated from a flexible heat shrinking polymer.

Claim 7 (rejected): The tissue removal device of claim 6, wherein the sheath is in the form of at least one of a mesh, net and lattice.

Claim 8 (rejected): The tissue removal device of claim 4, further comprising an actuation system operatively connected to the sheath in order to facilitate removal of the sheath from the bag assembly.

Claim 9 (rejected): The tissue removal device of claim 8, wherein the actuation system includes a tear line formed in the sheath to facilitate tearing of the sheath.

Claim 10 (rejected): The tissue removal device of claim 9, wherein the actuation system includes a cord operatively connected to the tear line for facilitating the tearing of the sheath along the tear line.

Claim 11 (rejected): The tissue removal device of claim 10, wherein the cord is connected to a control portion at the proximal end of the shaft.

Claim 12 (rejected): The tissue removal device of claim 9, wherein the actuation system includes an expandable member positioned within the bag assembly.

Claim 13 (rejected): The tissue removal device of claim 12, wherein expansion of the expandable member is initiated remotely from the bag.

Claim 14 (rejected): The tissue removal device of claim 1, wherein the bag has a proximal edge and a distal edge and includes a slot formed in the vicinity of the bag support near the proximal edge to enable the diameter of the bag to be adjusted.

Claim 15 (rejected): The tissue removal device of claim 14, wherein the bag includes a control line for drawing the slot closed.

Claim 16 (rejected): The tissue removal device of claim 1, wherein the bag is conical in shape.

Claim 17 (rejected): The tissue removal device of claim 1, wherein the bag is trapezoidal in shape.

Claim 18 (rejected): The tissue removal device of claim 1, further comprising a control portion operatively coupled to the proximal end of the shaft.

Claim 19 (rejected): A method of collapsing a bag of a tissue removal device, the method comprising the steps of:

providing a minimally invasive tissue removal device including:

a shaft having a distal end and a proximal end and defining a longitudinal axis;

a bag support; and

a bag attached to the bag support and being repositionable between an unfolded position, in which the bag extends away from the bag support, and a folded position, in which the bag is folded onto itself, the bag having a first edge and a second edge, an upper end operatively coupled to the bag support and a lower end; and

folding the bag transversely with respect to the longitudinal axis such that a first transverse fold is formed that extends at least partially from the first edge toward the second edge such that an angle less than 90° is defined relative to the longitudinal axis longitudinal axis, whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold.

Claim 20 (rejected): The method according to claim 19, wherein the bag is folded onto itself such that the proximal edge crosses the distal edge.

Claim 21 (rejected): The method according to claim 19, wherein the step of folding the bag further comprises folding the bag such that at least one subsequent fold is formed, the at least one subsequent fold being approximately parallel to the longitudinal axis.

Claim 22 (rejected): The method according to claim 19, wherein the bag support has a collapsed position and an expanded position and further comprising closing the upper end of the bag using the support.

Claim 23 (rejected): The method according to claim 22, wherein the bag is folded onto itself such that the proximal terminal edge of the bag is substantially parallel with the longitudinal axis.

Claim 24 (rejected): The method according to claim 19, wherein the bag is folded onto itself such that the proximal terminal edge of the bag is substantially aligned with the longitudinal axis.

Claim 25 (rejected): The method according to claim 20, wherein the bag is folded so that a portion of the bag is disposed distally of a distal end of the support.

Claim 26 (rejected): The method according to claim 19, further comprising the step of placing the folded bag and bag structure into a sheath.

Claim 27 (rejected): The method according to claim 26, wherein the sheath includes a weakness and further comprising tearing the sheath at the weakness so as to release the bag.

Claim 28 (rejected): A minimally invasive tissue removal device for passage through a cannula, the device comprising:

an elongate shaft having a distal end portion and a proximal end portion, the elongate shaft defining a longitudinal axis; and

a bag assembly operatively coupled to the distal end portion of the shaft, the bag assembly including:

a bag support structure having a first position and a second position; and

a bag configured for repositioning between an unfolded position, in which the bag extends away from the bag support, and a folded position, in which the bag is folded onto itself, the bag having an upper end and a lower end, the upper end having an open position and a closed position and being operatively secured to the bag support such that when the bag support is in the open position, the upper end of the bag is substantially open and when the bag support is in the closed position, the upper end of the bag is substantially closed;

the bag being folded over onto itself so as to form at least one transverse fold defining a fold axis, wherein the fold axis defines an angle between 0° and 90° relative to the longitudinal axis such that an axial length of the bag assembly is increased and a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the

folded position, that is relatively smaller as compared to a distal portion of the tissue removal device including a like bag, in a folded position, that is devoid of said at least one transverse fold.

Claim 29 (rejected): The tissue removal device according to claim 28, further comprising a removable sheath disposed about the bag assembly when in the bag is in the folded condition.

Claim 30 (rejected): The tissue removal device according to claim 29, wherein the bag has a proximal edge and a distal edge and wherein the bag is folded such that the proximal edge is substantially aligned with the longitudinal axis.

Claim 31 (rejected): A minimally invasive tissue removal device for passage through a trocar, the device comprising:

an elongate shaft having a distal end portion and a proximal end portion, the elongate shaft defining a longitudinal axis;

a bag support at the distal end of the shaft having a first position and a second position, the bag defining a plane in the first position; and

a bag having an open end and a closed end opposite the open end, the bag extending along a bag axis which is perpendicular to the longitudinal axis, the bag having an open position and a closed position and being configured for repositioning between an unfolded position, in which the bag extends away from the bag support, and a folded position, in which the bag is folded onto itself;

wherein the bag is folded over onto itself so as to form at least one fold extending along an axis that is substantially non-parallel and non-orthogonal to the longitudinal axis of the shaft, whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold.

Claim 32 (rejected): The tissue removal device of claim 31, wherein the bag is folded into a cylinder adjacent the bag support.

Claim 33 (rejected): A method of collapsing a bag of a tissue removal device, the method comprising the steps of:

providing a minimally invasive tissue removal device having a bag assembly including:

a shaft defining a longitudinal axis;

a bag support disposed at a distal end of the shaft; and

a bag attached to the bag support, the bag being repositionable between an unfolded position, in which the bag assembly defines an initial longitudinal dimension, and a folded position, in which the bag assembly defines a subsequent longitudinal dimension, the subsequent longitudinal dimension being greater than the initial longitudinal dimension; and

folding the bag such that at least one transverse fold is formed, the at least one transverse fold extending transversely with respect to the longitudinal axis, whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the

distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold.

Claim 34 (rejected): The method according to claim 33, wherein the step of folding the bag further comprises folding the bag such that at least one subsequent fold is formed, the at least one subsequent fold extending along an axis that is approximately parallel to the longitudinal axis.

Claim 35 (rejected): The method according to claim 34, wherein the step of folding the bag such that at least one subsequent fold is formed includes folding the bag such that a cross-sectional profile of the bag assembly is minimized when the bag is in the folded position.

IX. EVIDENCE APPENDIX

None

X. RELATED PROCEEDINGS APPENDIX

None